To: Betty Hiner@DFSR@FDAORAHQ

Cc: Bcc:

From: "Brenda Czaya" <CZAYA@ibm.net>

Subject: Docket No. 98-N-1265

Date: Tuesday, May 4, 1999 at 3:25:13 pm EDT

Attach: ()170 '99 MAY 14 P2:06 Certify: N

Dear Ms. Hiner

I read with some alarm that the FDA is considering limiting legal compounded prescriptions, written by physicians, for personal use, across state lines.

Why???

I am a 50 year old woman, still having regular periods, yet with low levels of estrogen, progesterone, testosterone, and DHEA. In addition, I have osteopenia. Pharmaceutical companies do not make patches or pills in the right dosages for me, using bio-identical hormones. With compounded products, my symptoms have been alleviated, and I am now slowing my rate of bone loss. As I march toward menopause, this next exciting phase of my life, I know my physician can change my prescriptions incrementally as I need it.

You would deprive me of the best solution my health has ever had. Women are not "one size fits all." As the millions of baby boomers behind me reach my age, they will insist on being treated as individuals, with individual hormone levels, and will want bio-identical, not moleculary altered "products."

Perhaps then the pharmaceutical companies will wake up and realize that millions of women do poorly on horse urine and progestins and make more bio-identical products available.

Until then, *please* don't take away my ability to have access to compounded products which have relieved my depression and lifted the mental fog, and which are now positively impacting my bone loss. There are few comprehensive compounding pharmacies knowleadgeable in women's hormones. Please don't deny me my health because I live in the wrong state. This would compromise my quality of life. Please don't listen to the big pharmaceutical interests—if they've missed the boat on bio-identical products, let them catch up—don't penalize me or the compounding pharmacies.

Thank you

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